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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/643,424

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Joseph P. Fredrick

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EXAMINER

GORDON, BRIAN R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/643,424	<b>Applicant(s)</b> FREDRICK, JOSEPH P.	
	<b>Examiner</b> Brian R. Gordon	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 8-11, 13-16, 18, 29-36, 46, 48-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 8-11, 13-16, 46, 48-50, 52 and 53 is/are allowed.
- 6) ☒ Claim(s) 18, 29-36, and 54-55 is/are rejected.
- 7) ☐ Claim(s) 51 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed July 15, 2008 have been fully considered but they are not persuasive.

It should be noted that step (c) of claim 29 implies that some effective controlling of the level of hydrophilicity or hydrophobicity is occurs. However as stated in the previous office action no such controlling is supported by the specification. The step only requires a separation of the liquid from the substrate or vice versa. Whether or not drops are formed during the removal step will depend upon a number of factors besides those based upon properties of the substrate. For example, the properties of the reagent (such as viscosity), removal speed (of the liquid or substrate). The claims do not provide any such specifics to determine what the requirements are such as to prevent residual drops remaining on the substrate. Furthermore, the claim does not require that no drops be formed on the substrate. The claim only requires the formation of the droplets to be limited. The examiner asserts that Any removal process will "limit" the formation of droplets remaining on the substrate. The removing the liquid/substrate results in less droplets being present on the substrate. The term "limit" is relative. The limit the formation of droplets in comparison to what?

Step (b) of claim 29 (and claim 30) states "said step". It is unclear if the phrase is directed to step (a) or the "step" referenced in the preamble. Step (c) of claim 29 states "said fluid". It is assumed the passage is directed to the "reagent fluid".

As to claim 29 applicant asserts Loeffler et al., McGrath et al., and Takeuchi do not show the removing step. Applicant further asserts that based upon Richardson v. Sususki Motor Co. the identical invention must be shown. It must be noted the facts of the Richardson case are different from that as related to instant invention. The Richardson case or quote applicant is referencing was directed to jury instructions given for considering the structure of motorcycle suspensions. The case does not address as method.

However, Loeffler et al. discloses a step of removing. (see abstract; column 3, lines 36-40, 45-48). Furthermore, the entire paragraph at column 3, line 57 - column 4, line 15 details a method of how fluid enters and is removed from the chamber.

McGrath et al. also teaches the removing step. (see last line of the abstract; column 1, lines 26-29, column 8, lines 6-9; and column 11, line 62 - column 12 line 10).

Takeuchi et al. discloses a washing process that uses a washing liquid that involves bring the washing liquid (water) in and out contact with the slides. (column 5, lines 30-45). Furthermore the reference teaches lowering/immersing slides in vessels containing liquids and removing the slides therefrom. (column 6, lines 45-55; column 7, lines 4-8).

For the reasons given herein above, the previous rejections are hereby maintained.

### ***Double Patenting***

2. Claim 51 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 48. When two claims in an application are duplicates or else are so close in

content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The only difference in claim 51 is the recited intended use of the wedge.

***Claim Rejections - 35 USC § 112***

3. Claims 18 and 54-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 54-55 are not further structurally limiting.

As to claim 18, the array is not positively claimed as an element of the device.

The array is not considered an element of the device, but is a structure one intends to be used with the claimed device.

Applicant has amended claims 54 and 55 by deleting the structure of the computer controls. The "controlled manner" is not a structure, but a narrative of intended use or desired method of use of the device.

***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 29-30, 32, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Loeffler et al. US 6,673,620.

Loeffler et al. disclose a sample chamber is formed by a housing sealed against a microscope slide. The housing has fluid ports, including a well formed over at least one port. In a rinse station, rinse solution is drawn from a reservoir through the chamber to a waste reservoir. At a fill station, an aliquot of reagent already placed in the well is driven into the chamber. The reagent may be driven into the chamber by first drawing a vacuum on the chamber through the aliquot of reagent and then releasing the reagent to be drawn into the chamber by the vacuum (abstract).

In embodiments of the present invention, a fluid handling apparatus is capable of spreading small amounts of liquid reagent over a flat surface, such as a microscope glass slide. The reagent may be sealed within a confined cavity, or "chamber", so as to prevent evaporation even with heating of small amounts of reagent during an incubation period. One surface of this chamber is the flat slide surface. The remaining surfaces are formed by a cell. The cell is preferably a plastic disposable part that fits on top of the slide, over the area containing the tissue, biologic cells, or array mounted on the glass slide. The cell forms a fluid seal to the surface of the glass by means of a gasket. The gasket is mounted in a recess on the face of the cell that mates with the glass slide.

In another method of fluid injection, reagent is placed into the reagent well, as before. A fluid injector is positioned above the fluid inlet port. In addition, the fluid aspirator is positioned above the fluid outlet port. The valves of both fluid ports are opened by this process. Reagent is then pushed into the chamber by a burst of air pressure. The transient, high-pressure reagent injection avoids entrapping bubbles by forcing laminar flow of reagent through the chamber. Once the reagent completely fills

the chamber, the pressure is removed and the valves are closed by disengaging the fluid injector and fluid aspirator.

Thus, in accordance with one aspect of the invention, an apparatus (fluid separation mechanism) for adding and removing liquid reagents to and from a sample comprises a flat surface supporting the sample and a chamber forming a cavity on the flat surface, the chamber being releasably sealed to the flat surface. Fluids can be added or removed through a fluid port in the wall of the chamber. A source of negative or positive air pressure is provided in a conduit, and an actuator is able to move the fluid port and conduit relative to each other to engage the conduit and fluid ports to each other so that the two are in fluid communication.

FIG. 11 is a perspective representation of an instrument 43 that incorporates positions for eight slides. The instrument 43 is shown with ISH cells in each of the eight positions. Each of the hinged covers 17 is clamped downwards underneath the latch 15. A heater controller pad 45 is located on the front panel of the instrument 43. The heater controller (temperature controller) pad allows someone using the instrument 43 to enter a desired temperature to which the heaters will be heated.

6. Claims 29-36 are rejected under 35 U.S.C. 102(b) as being anticipated by McGrath et al. US 5,192,503.

McGrath et al. discloses an automated assay analysis method and a probe clip for in situ assay of tissue sections in the form of a plate having a first seal member mounted thereon and forming an interior cavity on the plate. In one embodiment, a second seal member is mounted interiorly of the first seal member and divides the

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interior cavity into first and second fluid communicatable surfaces, with a probe dryingly attached to the plate and disposed on the second mixing surface. The plate is joined to a slide carrying a tissue section and a reactant fluid such to form fluid communicatable reaction and mixing chambers. Successive rotations of the joined plate and slide causes the reactant fluid to initially flow to the mixing chamber and release the probe, before the probe flows to the reaction chamber for reaction with the tissue section. In another embodiment, a time-release material covers the probe mounted on a plate having a single chamber. The reactant fluid hydrolyzes the time-release material to release the probe for reaction with the tissue. The cassette carrying one or more plates is slidingly insertable into a semi-closed housing containing one or more tissue-carrying slides. Clamps urge the probe clip cassette and the individual plates into engagement with the slides to form the sealed chambers therebetween. Inlet and outlet wash ports communicate with the slides to wash the slides after the plates have been removed from the housing (abstract).

The wash means includes an inlet port 178 and an outlet port 180 associated with each receptacle in the case 73, as shown in FIG. 3 and in greater detail in FIG. 9. Each inlet port 178 and outlet port 180 extends through the front wall 130 of the case 73. The inlet port 178 comprises a hollow tube or conduit which opens into the interior of the case 73 in each receptacle. The inlet port 178 is positioned below the slide support members 152 mounted on the base of the case 73. The slide support members 152 extend above the bottom of the case 73 and define a chamber 176 below the slide 50 mounted on the slide support members 152.



The outlet port 180 is connected to a conduit 182 which extends through the case 73 and terminates adjacent the back wall 128. The terminal end of the conduit 182 opens to the interior of the case 73 in the receptacle so as to receive fluid from above and below the slide 50 mounted on the slide receiving members 152. In this manner, all of the fluid within each receptacle may be removed by tilting or disposing the case 73 vertically with the front wall 130 being positioned in a downward facing direction or by applying a vacuum or suction force to the outlet port 180 to draw all the fluid from the receptacle (separation mechanism). In this manner, the slide 50 in each individual receptacle in the case 73 may be individually washed so as to remove all traces of unreacted probe from the tissue 52 mounted on the slide 50 without contaminating adjacent samples (column 11, lines 51+).

7. Claims 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi, US 4,738,824.

Takeuchi discloses an automatic dyeing apparatus M for dyeing specimens such as tissue or cell has a casing 1, in the upper portion of which a horizontal main table 2 is provided for disposing regularly many vessels v, v, . . . v thereon, each containing a kind of liquid such as reagent and water for dyeing specimens. Each vessel v has an open top face through which a specimen cage 3 for supporting many pieces of slide glass with specimens is immersed into the reagent or water of each vessel v. On the upper face of the casing 1 is provided a specimen cage transporting mechanism T (separating mechanism) for transporting specimen cages into the respective vessels v. The mechanism T has a first slide body 4 extending laterally over the vessels v arranged on

the main table 2 and the first slide body 4 is moved in the longitudinal direction (X direction) of the casing 1 while its opposite ends slide on respective guide rails 5, 5. Further, the first slide body 4 has a second slide body 6 extending vertically which is moved along the first slide body 4 in the lateral direction (Y direction) of the casing 1. The second slide body 6 has a support head 7 for supporting a specimen cage and the support head 7 is moved vertically along the second slide body 6 in the vertical direction (Z direction). The two slide bodies 4, 6 have two slits 4a, 6a formed on one side wall of their respective casings and one end of the first slide body 4 is moved along a slit 8a provided in an upper casing 8 which is formed on the back side of the upper portion of the casing 1. The casing 1 accommodates a plurality of reagent tanks 9a, 9b, . . . , 9e at its bottom (column 2, lines 21+).

In both groups, 1 and 2, the vessels have two inlets 23, 24, respectively, through which xylene in a tank 9a is supplied into the respective via a pump 25, two valves 26, 26 and two nozzles 27, 27 for adjusting flow rate of xylene. The vessels have two outlets 28, 28 for discharging used xylene.

In case that a plurality of dyeing reagents are used, a washing process must be carried out between the immersions of a dyeing reagent and a next dyeing reagent. After the specimen is dyed in the dyeing reagent, the specimen is washed by the normal water and/or the distilled water.

***Allowable Subject Matter***

8. Claims 2, 8-11, 13-16, 46, 48-50 and 52-53 are allowed.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/  
Primary Examiner  
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